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NEVADA STATE HEALTH DIVISION NEWS RELEASE H1N1 Vaccine Update

Carson City – The Nevada State Health Division announced today that a minimal amount of the recent non-safety related voluntary recall of certain lots of Sanofi Pasteur H1N1 pediatric vaccine was distributed to providers in Nevada.

“There are no safety concerns with these lots of H1N1 vaccine. All of the affected lots successfully passed pre-release testing for purity, potency and safety. Parents of children who received vaccine from the recalled lots do not need to take any action,” State Health Officer Tracey D. Green said. “Infants and children who received vaccines from these lots **do not** need to be revaccinated. All children under the age of 10 will still need to get their H1N1 booster shot, 28 days after receiving the initial shot.”

As part of its quality assurance program, Sanofi Pasteur, Inc., performs additional routine, ongoing testing of influenza vaccines after the vaccine has been distributed to health care providers to ensure that vaccines continue to meet required specifications. In recent testing of the amount of antigen in its influenza A (H1N1) vaccine, Sanofi Pasteur found four distributed lots of single-dose, pre-filled syringe pediatric (0.25 mL) vaccine with antigen content lower than the required potency levels.

While the antigen content of these lots is now below the specification limit for the product, the Centers for Disease Control and Prevention (CDC) and the federal Food and Drug Administration (FDA) are in agreement that the small decrease in antigen content is unlikely to result in a clinically significant reduction in immune response among persons who have received the vaccine.

Approximately 2,400 doses of the voluntarily recalled H1N1 vaccine were shipped to providers in Nevada. Providers are being asked to return any vaccine that remains unused to the manufacturer from the specified lots. Southern Nevada Health District, Washoe County Health District and Carson City Health and Human Services did not receive any of the affected lots. The Health Division’s Immunization Program staff are currently notifying the providers that received the recalled vaccine.

For more information go to: <http://flu.nv.gov>

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A handwritten signature in blue ink that reads "Tracey Green MD".

Tracey D. Green, State Health Officer

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